

basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist.

(1) Check “Negative” (Step 6) on the CCF.

(2) Sign and date the CCF.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding results of both the evaluation conducted under § 40.193(d) and any further medical examination. This report must state that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*i.e.*, the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test is needed for that purpose).

(d) For purposes of this section, permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.

(1) Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genito-urinary matters.

(2) Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in paragraph (d)(1) of this section.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.197 What happens when an employer receives a report of a dilute specimen?

(a) As the employer, if the MRO informs you that a positive drug test was dilute, you simply treat the test as a verified positive test. You must not direct the employee to take another test based on the fact that the specimen was dilute.

(b) As an employer, if the MRO informs you that a negative test was dilute, take the following action:

(1) If the MRO directs you to conduct a recollection under direct observation (*i.e.*, because the creatinine concentration of the specimen was equal to or greater than 2mg/dL, but less than or equal to 5 mg/dL (*see* § 40.155(c)), you must do so immediately.

(2) Otherwise (*i.e.*, if the creatinine concentration of the dilute specimen is greater than 5 mg/dL), you may, but are not required to, direct the employee to take another test immediately.

(i) Such recollections must not be collected under direct observation, unless there is another basis for use of direct observation (*see* § 40.67 (b) and (c)).

(ii) You must treat all employees the same for this purpose. For example, you must not retest some employees and not others. You may, however, establish different policies for different types of tests (*e.g.*, conduct retests in pre-employment situations, but not in random test situations). You must inform your employees in advance of your decisions on these matters.

(c) The following provisions apply to all tests you direct an employee to take under paragraph (b) of this section:

(1) You must ensure that the employee is given the minimum possible advance notice that he or she must go to the collection site;

(2) You must treat the result of the test you directed the employee to take under paragraph (b) of this section—and not a prior test—as the test result of record, on which you rely for purposes of this part;

(3) If the result of the test you directed the employee to take under paragraph (b)(1) of this section is also negative and dilute, you are not permitted to make the employee take an

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additional test because the result was dilute.

(4) If the result of the test you directed the employee to take under paragraph (b)(2) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute. Provided, however, that if the MRO directs you to conduct a recollection under direct observation under paragraph (b)(1) of this section, you must immediately do so.

(5) If the employee declines to take a test you directed him or her to take under paragraph (b) of this section, the employee has refused the test for purposes of this part and DOT agency regulations.

[68 FR 31626, May 28, 2003, as amended at 69 FR 64867, Nov. 9, 2004; 73 FR 35974, June 25, 2008]

§ 40.199 What problems always cause a drug test to be cancelled?

(a) As the MRO, when the laboratory discovers a “fatal flaw” during its processing of incoming specimens (see § 40.83), the laboratory will report to you that the specimen has been “Rejected for Testing” (with the reason stated). You must always cancel such a test.

(b) The following are “fatal flaws”:

(1) There is no printed collector’s name *and* no collector’s signature;

(2) The specimen ID numbers on the specimen bottle and the CCF do not match;

(3) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be redesignated, see § 40.83(g)); and

(4) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be redesignated (see § 40.83(g)).

(c) You must report the result as provided in § 40.161 .

§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

As the MRO, you must cancel a drug test when a laboratory reports that any of the following problems have occurred. You must inform the DER that

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the test was cancelled. You must also direct the DER to ensure that an additional collection occurs immediately, if required by the applicable procedures specified in paragraphs (a) through (e) of this section.

(a) The laboratory reports an “Invalid Result.” You must follow applicable procedures in § 40.159 (recollection under direct observation may be required).

(b) The laboratory reports the result as “Rejected for Testing.” You must follow applicable procedures in § 40.161 (a recollection may be required).

(c) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. You must follow the applicable procedures in § 40.187(b)—no recollection is required in this case, unless the split specimen creatinine concentration for a substituted primary specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/ dL, or the primary specimen had an invalid result which was not reported to the DER. Both these cases require recollection under direct observation.

(d) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results, and that the split specimen was invalid. You must follow the procedures in § 40.187(c)(1)—recollection under direct observation is required in this case.

(e) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the split specimen was not available for testing or there was no split laboratory available to test the specimen. You must follow the applicable procedures in § 40.187(e)—recollection under direct observation is required in this case.

(f) The examining physician has determined that there is an acceptable medical explanation of the employee’s failure to provide a sufficient amount of urine. You must follow applicable procedures in § 40.193(d)(1) (no recollection is required in this case).

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35974, June 25, 2008]